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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,892	11/26/2003	Lucie Minarikova	MIL-002	1154
3897	7590	03/30/2005	EXAMINER	
SCHNECK & SCHNECK P.O. BOX 2-E SAN JOSE, CA 95109-0005			VESTAL, REBECCA MICHELLE	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/723,892

Applicant(s)

MINARIKOVA, LUCIE

Examiner

R. Michelle Vestal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/13/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: Figures 3A and 3B are not listed in the Description of the Drawings section.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 6,174,675 to Chow et al. (Chow).

Regarding claim 1, Chow discloses a method for capillary separation of a sample (Col. 41, lines 13-17) comprising:

- injecting the sample into a separation channel (Col. 41, lines 62-66);
- electrophoretically separating the sample in the separation channel (Col. 41, lines 56-58);
- exposing the separation channel to a cycling temperature gradient while electrophoretically separating the sample (Col. 41, lines 55-56 and Col. 42, lines 2-3);
- and
- detecting separated compounds in said sample (Col. 41, lines 58-62).

Chow discloses the limitations of claim 2, wherein said separation channel a capillary tube (Col. 3, lines 45-51).

Chow discloses the limitations of claim 4, wherein said separation channel is on a micro-fabricated substrate (Fig. 22 and Col. 1, lines 31-47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (citation "AM" from applicant's Information Disclosure Statement) in view of Chow.

Regarding claim 1, Li discloses a method for capillary separation of a sample (page 1502, left column, second paragraph) comprising:

injecting the sample into a separation channel (page 1502, left column, second paragraph);

electrophoretically separating the sample in the separation channel (page 1502, left column, second paragraph);

exposing the separation channel to a temperature gradient while electrophoretically separating the sample (page 1502, right column, first paragraph); and

detecting separated compounds in said sample (page 1502, right column, second paragraph).

Li does not disclose expressly that a cyclic temperature gradient is employed.

Chow teaches the use of cyclic temperature ramps in a microfluidic system (Col. 33, lines 48-57), such as capillary electrophoresis (Col. 1, lines 48-51). Chow also teaches the thermal denaturation of DNA in successive cycles to generate large quantities of the required nucleic acid sequence from even a single molecule of starting material (Col. 33, lines 34-41).

Li and Chow are analogous art because they are from the same field of endeavor, that is microfluidic channel platforms.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to cycle the temperature gradient in the method of capillary separation of Li because large quantities of DNA variants can be produced and detected from very small quantities of starting material, as taught by Chow (Col. 33, lines 34-36). The use of very small volumes of sample is desirable for reagent economy and integrating the amplification process would reduce the amount of time required for analysis (Col. 34, lines 8-14). Chow also teaches that the use of a capillary channel for the DNA amplification prevents evaporation of liquid, which is a common problem associated with previous techniques (Col. 34, lines 4-8).

Therefore, it would have been obvious to combine Li with Chow to obtain the invention as specified in claim 1.

Li discloses the limitations of claim 2, wherein said separation channel a capillary tube (page 1501, left column, second paragraph).

Li discloses the limitations of claim 3, wherein the method further comprises repeating all steps of claim 1 in a plurality of capillaries in a capillary array (page 1501, left column, second paragraph).

Li discloses the limitations of claim 4, wherein said separation channel is on a micro-fabricated substrate (Figure 1 and page 1501, left column, second paragraph).

Li discloses the limitations of claim 5, wherein said micro-fabricated substrate includes a plurality of separation channels and steps of claim 1 are repeated in each channel (Figure 1 and page 1501, left column, second paragraph).

Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansfield (citation "AB" from applicant's Information Disclosure Statement) in view of Chow.

Regarding claim 6, Mansfield discloses a method for separating compounds (Col. 5, lines 19-24) comprising:

- a) injecting a sample into a separation channel (Fig. 2, step 17);
- b) migrating the sample for a specified interval (Fig. 2, step 47);
- c) repeating steps a and b a plurality of times (Fig. 2, step 51); and
- d) following a final sample injection, continuously detecting separated samples (Fig. 2, step 55).

Mansfield does not disclose expressly that the separation channel is exposed to a temperature gradient.

Chow teaches the use of cyclic temperature ramps in a microfluidic system (Col. 33, lines 48-57), such as capillary electrophoresis (Col. 1, lines 48-51). Chow also teaches the thermal denaturation of DNA in successive cycles to generate large quantities of the required nucleic acid sequence from a single molecule of starting material (Col. 33, lines 34-41).

Mansfield and Chow are analogous art because they are from the same field of endeavor, that is microfluidic channel platforms.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to expose the separation channel to a cyclic temperature gradient in the

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method of separating compounds of Mansfield because large quantities of DNA variants can be produced and detected from very small quantities of starting material, as taught by Chow (Col. 33, lines 34-36). The use of very small volumes of sample is desirable for reagent economy and integrating the amplification process would reduce the amount of time required for analysis (Col. 34, lines 8-14). Chow also teaches that the use of a capillary channel for the DNA amplification prevents evaporation of liquid, which is a common problem associated with previous techniques (Col. 34, lines 4-8).

Therefore, it would have been obvious to combine Mansfield with Chow to obtain the invention as specified in claim 6.

Mansfield discloses the limitations of claim 7, wherein said separation channel is capillary tube (Col. 5, lines 29-31).

Mansfield discloses the limitations of claim 8, wherein the method further comprises repeating all steps of claim 6 in a plurality of capillaries in a capillary array (Col. 5, lines 29-31 and Figure 2).

Mansfield discloses the limitations of claim 9, wherein said separation channel is on a micro-fabricated substrate (Col. 15, lines 39-52).

Mansfield discloses the limitations of claim 10, wherein said micro-fabricated substrate includes a plurality of separation channels and steps of claim 1 are repeated in each channel (Col. 15, line 39-Col. 16, line 6).

Regarding claims 11 and 12, Mansfield does not disclose expressly that the separation channel is exposed to a temperature gradient.

Chow teaches the use of cyclic temperature ramps in a microfluidic system, wherein the cycling temperature gradient has identical duration and temperature range cycles (Col. 33, lines 48-57) or wherein the cycling temperature gradient has variable duration or temperature range cycles (Col. 41, lines 5-6). Chow also teaches that there are variations in thermal denaturation rates among different proteins or different nucleic acids depending on their structure (Col. 35, lines 25-34).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to expose the separation channel to a cyclic temperature gradient with identical duration and temperature range cycles in the method of separating compounds of Mansfield because large quantities of a particular DNA variant can be produced and detected from very small quantities of starting material, as taught by Chow (Col. 33, lines 34-36). It would have been obvious to expose the separation channel to a cyclic temperature gradient with variable duration or temperature range cycles in the method of separating compounds of Mansfield because different proteins or nucleic acids may

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be amplified in the various cycles (or alternatively, certain proteins or nucleic acids may experience no or only limited amplification) based on the particular temperature or duration of the cycle, as taught by Chow (Col. 35, lines 25-44). The use of very small volumes of sample is desirable for reagent economy (Col. 34, lines 8-14) and integrating the amplification process would simplify and reduce the amount of time required for analysis (Col. 41, lines 13-17). Chow also teaches that the use of a capillary channel for the DNA amplification prevents evaporation of liquid, which is a common problem associated with previous techniques (Col. 34, lines 4-8).

Therefore, it would have been obvious to combine Mansfield with Chow to obtain the inventions as specified in claims 11 and 12.

Conclusion

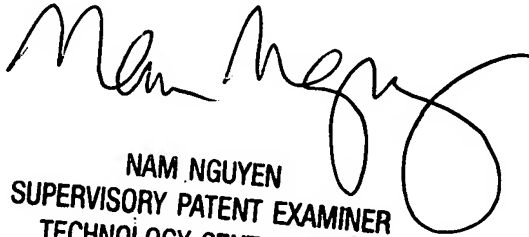
Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Michelle Vestal whose telephone number is (571) 272-0524. The examiner can normally be reached on Monday-Friday, 8am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rmv/rmv
March 14, 2005


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